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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,909	11/17/2000	Ronald D. Flannagan	35718/204664	5613

29122 7590 01/31/2005

ALSTON & BIRD LLP
PIONEER HI-BRED INTERNATIONAL, INC.
BANK OF AMERICA PLAZA
101 SOUTH TYRON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/715,909	Applicant(s) FLANNAGAN ET AL.	
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,10-18,28-32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,10-18,28,29,32,34,35 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 30,31 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/04 has been entered.
2. The rejection of claims 1(f)-3, 7(f)-8, 10-18 & 32 under 35 U.S.C. 112, first paragraph, for new matter for the recitation related "comprising the ligand binding site..." is withdrawn due to the amendment of the claims.
3. The rejection of claims 7-8 & 33-36 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "polypeptides of interest" is withdrawn due to the cancellation or amendment of the claims.
4. The rejection of claims 1-3, 7-8, 10-18 & 32 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "set forth as amino acids 4038-4547 of *SEQ ID NO: 2*" is withdrawn due to the cancellation or amendment of the claims.

5. Applicants' arguments filed 11/10/04 have been considered but were not found persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The Yu Declaration under 37 CFR 1.132 filed 11/10/04 is insufficient to overcome the rejection of the pending claims based upon lack of written description as set forth in the last Office action because: Declarant ignores that the reason for the instant rejection is that the single disclosed nucleotide molecule of SEQ ID NO: 1 (or the encoded "toxin-binding site of the *ECB* *Bt* toxin receptor" contained within SEQ ID NO: 2) is clearly not representative of the claimed insect genus. In other words, the skilled artisan cannot reasonably visualize what nucleotide sequences would encode the insect variant sequences claimed, because a single insect species is not reasonably representative of all insects, or even a different insect species. Therefore, this declaration is not on point, and merely demonstrates that claim 1(f) is enabled (which is not the current rejection). In contrast, the current rejection is a rejection under 35 U.S.C. 112, first paragraph for lack of written description.

8. Claims 30-31 & 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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9. Claims 1-3, 7, 10-18, 28-29, 32, 34-35 & 37-39 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed, for the reason made of record in Paper NOs: 10 (mailed 2/13/02), 13 (mailed 10/18/02), 16 (mailed 4/07/03), 21 (mailed 11/17/03) & 20040506, and as follows.

Applicants argue on pages 8-10 of the response that the claims “meet the requirements for written description under the *Guidelines* and *Enzo* because they provide the relevant, identifying characteristics, including partial structure and functional characteristics, of the claimed polypeptides”, and cites *Ex parte Sun* and *Ex parte Vogelstein*. In contrast to Applicants’ assertions, it is stated at the top of both *Ex parte Sun* and *Ex parte Vogelstein* that “The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board” [emphasis added]. In other words, each case is decided upon its own merits; especially when the fact situation differs. Moreover, the issue remains that the single disclosed species of an *Ostrinia nubilalis* receptor nucleic acid molecule of SEQ ID NO: 1 is not reasonably representative of the *Lepidopteran* order/genus claimed; thereby, not reasonably providing written description of the claimed genus. As previously made of record, the specification fails to describe a single other nucleic acid molecule that reasonably would be representative of a different insect species within the *Lepidopteran* order, or even within the *Pyraloidea* superfamily. Therefore, the pending rejection is consistent with the current *Guidelines*, and that held by the court in *Enzo*, and in *Fiers v. Revel* and *Univ. California v. Eli*

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Lilly and Co. previously made of record. Thus, Applicants are clearly not in possession of the claimed genus of *Lepidopteran* insect receptor nucleic acid molecules claimed, for the reasons made of record. See again MPEP 2163.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
January 25, 2005

ROBERT C. HAYES, PH.D.
PATENT EXAMINER